

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Jay Lahti	Examiner:	Alter, A.M.
Serial No.	10/632,026	Group Art Unit:	3762
Filing Date:	July 31, 2003	Docket No.:	P0011616.00
Title:	CONNECTOR ASSEMBLY FOR CONNECTING A LEAD AND AN IMPLANTABLE MEDICAL DEVICE		

Substitute Appeal Brief

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following Brief is submitted pursuant to the Notice of Appeal mailed August 4, 2009 and in response to the Notification of non-compliant appeal brief mailed October 26, 2009.

In addition to the deficiency in Section III noted by the Appeals Specialist, the previously submitted brief omitted the required discussion of the rejections of the claims based upon the prior art and addressed only the double patenting rejection. The present substitute brief also rectifies this error. As Sections II, III, VI and VII required amendment, a substitute brief containing all of sections I – VII is hereby submitted with the hopes that it will be easier to follow.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

I. Real party in interest

The real party in interest in this application is Medtronic, Inc, assignee of the application.

II. Related appeals and interferences

This appeal is related to the appeal in US Patent Application No. 10/632,058, filed July 31, 2003 by Ries, et al. for a "Small Format Clip of an Implantable device. The Notice of Appeal in the Ries, et al. application was filed on August 4, 2009, concurrent with the Notice of Appeal in the present application. As discussed below, the two applications are each subject to a double patenting rejection with regard to the other.

The present application is also subject to a rejection over the prior art. The Ries, et al. application is not.

III. Status of the claims

Claims 1, 3 – 17, 19 – 33 and 35 – 52 are pending. Claims 1, 3 – 17, 19 – 33 and 35 – 48 stand rejected for obviousness-type double patenting over the Ries, et al application cited above, for obviousness-type double patenting over now allowed US Patent Application Serial No. 10/632,028 and under Section 103 over the cited prior art . All rejections of claims 1, 3 – 17, 19 – 33 and 35 – 48 are appealed.

Claims 2, 18 and 34 are cancelled. Claims 49 – 52 are withdrawn due to a finding of constructive election in the Final Office Action. This election requirement was not traversed. These claims will be withdrawn upon indication of allowability of the appealed claims.

IV. Status of amendments

The Response mailed April 3, 2009 has been received by the Patent according to PAIR. No Advisory Action was mailed or received. The Notice of Appeal was filed when it became clear no Advisory Action would be mailed.

The response of April 3, 2009 contained no amendments to the claims.

The Appendix of Claims reflects the claims as rejected by the Final Office Action of February 4, 2009.

V. Summary of claimed subject matter

1. Claim 1

Claim 1 sets forth a connector assembly for detachably connecting a lead to an implantable medical device. The assembly comprises a connector block having a connector port to receive a proximal end of a lead inserted therein along an insertion axis of orientation. The connector block is illustrated in Figure 1 and is described generally in paragraph [0031].

The assembly further comprises a deflectable connector clip including a first arm, a second arm, and a top portion extending between the first arm and the second arm, the connector clip capable of being deflected, prior to insertion of the lead, from a first position corresponding to a first relative position of the first arm and the second arm to a second position corresponding to a second relative position of the first arm and the second arm. The clip is illustrated in Figures 3A – 3D. The two positions of the clip are illustrated in Figures 3A and 3C. The clip is described in paragraphs [0039 – 40]

The assembly finally requires a housing mounted within the connector block, the housing having a first annular member and a second annular member, the first member formed to be fixedly engaged with the second member to form an aperture in alignment with the connector port to receive the lead proximal end along the insertion axis, the

connector clip being enclosed within the housing, wherein the connector clip is positioned within one of the first member and the second member while in the second position, wherein the first arm extends from the top portion to a first end and the second arm extends from the top portion to a second end, and wherein the connector clip includes a first side wall along the first end and a second side wall along the second end, the end of the first arm and the end of the second arm being offset and partially overlapping so that the first side wall is adjacent to and engaged against the second side wall when the connector clip is in the first position, and the first arm and the second arm being partially spread apart so that the ends are non-overlapping and aligned so that the first end abuts the second end and the first side wall is not adjacent to and engaged against the second side wall when the connector clip is in the second position, the connector clip being oriented perpendicular to the insertion axis of orientation of the proximal end of a lead such that the arms, the non-overlapping ends of the arms, and the top portion together circumscribe an opening through which the proximal end of a lead passes during insertion. The housing is illustrated in Figures 2 and 4 which show the two annular members, their configurations as claimed and the location of the clips within the housing. These drawings are described in paragraphs [0037 – 38] and [0041], respectively.

2. Claim 17

Claim 17 sets forth An implantable medical device capable of being detachably connected to a lead. The device comprises a connector block having a connector port to receive a proximal end of a lead inserted therein along an insertion axis of orientation. The connector block is illustrated in Figure 1 and is described generally in paragraph [0031].

The device further comprises a first deflectable connector clip including a first arm, a second arm, and a top portion extending between the first arm and the second arm, the connector clip capable of being deflected, prior to insertion of the lead, from a first position corresponding to a first relative position of the first arm and the second arm to a second position corresponding to a second relative position of the first arm and the

second arm. The clip is illustrated in Figures 3A – 3D. The two positions of the clip are illustrated in Figures 3A and 3C. The clip is described in paragraphs [0039 – 40].

The device finally comprises a housing mounted within the connector block, the housing having a first annular member and a second annular member, the first member formed to be fixedly engaged with the second member to form an aperture in alignment with the connector port to receive the lead proximal end along the insertion axis, the connector clip being enclosed within the housing, wherein the connector clip is positioned within one of the first member and the second member while in the second position, wherein the first arm extends from the top portion to a first end and the second arm extends from the top portion to a second end, and wherein the connector clip includes a first side wall along the first end and a second side wall along the second end, the end of the first arm and the end of the second arm being offset and partially overlapping so that the first side wall is adjacent to and engaged against the second side wall when the connector clip is in the first position, and the first arm and the second arm being partially spread apart so that the ends are non-overlapping and aligned so that the first end abuts the second end and the first side wall is not adjacent to and engaged against the second side wall when the connector clip is in the second position, the connector clip being oriented perpendicular to the insertion axis of orientation of the proximal end of a lead such that the arms, the non-overlapping ends of the arms, and the top portion together circumscribe an opening through which the proximal end of a lead passes during insertion. The housing is illustrated in Figures 2 and 4 which show the two annular members, their configurations as claimed and the location of the clips within the housing. These drawings are described in paragraphs [0037 – 38] and [0041], respectively.

3. Claim 33.

Claim 33 sets forth an implantable medical device capable of being detachably connected to a lead. The device comprises a connector block having a connector port to receive a proximal end of a lead inserted therein along an insertion axis of

orientation. The connector block is illustrated in Figure 1 and is described generally in paragraph [0031].

The device further comprises a first deflectable connector clip and a second deflectable connector clip, each of the first connector clip and the second connector clip including a first arm, a second arm, and a top portion extending between the first arm and the second arm, and capable of being deflected, prior to insertion of the lead, from a first position corresponding to a first relative position of the first arm and the second arm to a second position corresponding to a second relative position of the first arm and the second arm. . The clip is illustrated in Figures 3A – 3D. The two positions of the clip are illustrated in Figures 3A and 3C. The clip is described in paragraphs [0039 – 40].

The device finally comprises a housing mounted within the connector block, the housing having a first annular member and a second annular member, wherein the first connector clip is positioned, while in the second position, within the first annular member and the second connector clip is positioned, while in the second position, within the second annular member and oriented generally orthogonally to the first connector clip, and the first member is formed to be fixedly engaged with the second member to form an aperture in alignment with the connector port to receive the lead proximal end along the insertion axis, the first connector clip and the second connector clip being enclosed within the housing, wherein, for each of the first connector clip and the second connector clip, the first arm extends from the top portion to a first end and the second arm extends from the top portion to a second end, and wherein each of the first connector clip and the second connector clip includes a first side wall along the first end and a second side wall along the second end, the end of the first arm and the end of the second arm being offset and partially overlapping so that the first side wall is adjacent to and engaged against the second side wall when the first connector clip and the second connector clip is in the first position, and the first arm and the second arm being partially spread apart so that the ends are non-overlapping and aligned so that the first end abuts the second end and the first side wall is not adjacent to and engaged against the

second side wall when the first connector clip and the second connector clip is in the second position, each of the connector clips being oriented perpendicular the insertion axis of orientation of the proximal end of a lead such that the arms,, the non-overlapping ends of the arms, and the top portion together circumscribe an opening through which the proximal end of a lead passes during insertion. The housing is illustrated in Figures 2 and 4 which show the two annular members, their configurations as claimed and the location of the clips within the housing. These drawings are described in paragraphs [0037 – 38] and [0041], respectively.

VI. Grounds of rejection to be reviewed on appeal

A. Rejection of Claims 1, 3 – 17, 19 – 33 and 35 – 48 for obviousness-type double patenting over the Ries, et al. application cited above.

This rejection is respectfully appealed.

B. Rejection of Claims 1, 3 – 17, 19 – 33 and 35 – 48 for obviousness-type double patenting over now allowed US Patent Application Serial No. 10/632,028.

This rejection is no longer appealed, as the cited patent application has now been allowed as per the Notice of Allowance dated October 19, 2009. However, as no allowable claims have been indicated in the present case, the submission of a terminal disclaimer would be premature.

C. Rejection of Claims 1, 3 – 17, 19 – 33 and 35 – 48 under Section 103 as unpatentable over US Patent No. 5, 769,671 issued to Lim alone or in view of US Patent No. 5,275,620 issued to Darby , et al.

This rejection is respectfully appealed.

VII. Argument

A. Rejection of Claims 1, 3 – 17, 19 – 33 and 35 – 48 for obviousness-type double patenting over the Ries, et al application cited above.

The Argument applies to all claims. Individual claims are not separately argued

All claims in the present application are presently indicated to be unpatentable and are finally rejected. The claims of the Ries, et al. application have all been finally rejected for obviousness type double patenting over the present application by the same Examiner. Applicants acknowledge that if and when allowable subject matter is indicated in the present application, the question of double patenting should be reviewed in the present case with respect to the Ries, et al. application, assuming the claims therein are actually subject to a Notice of Allowance by that time. However, a final rejection of the claims of the present case for double patenting is believed clearly improper under the present circumstances. The claims of the present application may change substantially during further prosecution and the Ries, et al. claims presently stand rejected.

Withdrawal of the double patenting rejection in the present application at least until allowance of claims in the Ries, et al application is respectfully requested.

B. Rejection of Claims 1, 3 – 17, 19 – 33 and 35 – 48 for obviousness-type double patenting over now allowed US Patent Application Serial No. 10/632,028.

Because the claims of this application are now indicated to be allowable, applicants stand ready to file a terminal disclaimer over this prior application when and if otherwise allowable claims in the present application are identified.

C. Rejection of Claims 1, 3 – 17, 19 – 33 and 35 – 48 under Section 103 as unpatentable over US Patent No. 5,769,671 issued to Lim alone or in view of US Patent No. 5,275,620 issued to Darby, et al.

The grounds of rejection apply to all claims. Individual claims are not separately argued

Lim indisputably fails to teach or suggest all limitations of independent claims 1, 17 and 33 directed to a connector assembly for detachably connecting a lead to an implantable medical device. In the Office action, it is conceded that Lim fails to disclose a connector assembly that includes a clip having two arms, the end of the first arm and the end of the second arm being offset and partially overlapping. See Final Office Action, page 8, paragraph 2.

The Office Action argues that it would have been obvious to “modify the touching free ends of a the clip of Lim clip since it was known in the art that overlapped free ends of a clip, such as a paper clip, provide the predictable results of support and reinforcement.” See Office Action, page 8, paragraph 2. The Applicants submit that it would not be obvious to modify Lim in view of a paper clip and thereby arrive at independent claim 1, 17 or 33.

Both the clip in he Lim patent and that of the present invention as claimed comprise a “connector clip being oriented perpendicular to the insertion axis of orientation of the proximal end of a lead such that the arms, the non-overlapping ends of the arms, and the top portion together circumscribe an opening through which the

proximal end of a lead passes during insertion". The Examiner specifically so states in the Final Office Action. However, in use a paper clip defines an such an opening parallel to the path along which the papers it connects are inserted. Its operational mechanism being directly contrary to that required by the claims, it cannot teach modification of a clip specifically required to work when oriented perpendicularly to the apparatus inserted therein.

Alternatively, the Office Action also argues that it would have been obvious to modify the free ends of the Lim clip with overlapping free ends as taught by Darby et al. as depicted in figure 5. See Office Action, Page 8, paragraph. 2. The Applicants also submit that it would not be obvious to modify Lim in view of a Darby, and arrive at the invention of independent claim 1.

The clip in Darby, et al. has a top portion and two arms with overlapping ends defining an opening therebetween. However, like the case of the paper clip, the lead is inserted parallel to the opening so defined rather than perpendicular to the opening as required by the claims and as in the Lim clip. Further, the mechanism of its operation, wherein the free ends themselves have openings through which the lead passes is contrary to the mechanism of both the Lim clip and the mechanism of the clip in the invention as presently claimed.

It is respectfully asserted that modifying the Lim clip in light of clips which work using entirely different mechanisms from the Lim clip cannot be properly argued to be obvious. The overlapping ends of the paper clip and the Darby et al clip are specifically designed useful in a context other than that of the presently claimed invention, and offer no obvious benefits or improvement relative to the Lim clip.

It is understood that the Examiner takes the position that such a modification is obvious because "it was known in the art that overlapping the free ends of a clip provide the predictable results of reinforcement and support for engaging a lead." (Page 8) This argument, however, clearly does not spring from the cited teaching of Lim, Brady, et al or the paper clip. The ends of the Lim clip do not even engage the lead when inserted

therethrough. Making them overlap as in the presently claimed invention would not change this basic fact. Indeed in the clip of the present invention the overlapping ends do not contact the lead when inserted. How can modifying the Lim clip as argued by the Examiner obviously produce "the predictable results of reinforcement and support for engaging a lead" when the invention as claimed does not even produce this result?

Because the benefits argued to make the proposed modification of Lim obvious aren't present in Lim as modified and aren't even found in the present invention, the Examiner's proposed modification cannot possibly predict such results. It is therefore respectfully asserted that the only source for a suggestion to modify Lim as proposed by the Examiner or for any benefit thereof must be found in the present application.

It is respectfully asserted that the arguments in the Final office action based on Lim are not supported by the references cited and are contrary to the teaching of Lim. Withdrawal of the rejection of claims 1, 17 and 33 and those claims dependent thereon is respectfully requested.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546 for entry of the instant Response.

Respectfully submitted,

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/ Reed A. Duthler/

Reed A. Duthler
Reg. 30,626
Telephone: (763) 526-1564
Customer No. 27581